NKDEP

National Kidney Disease Education Program

Laboratory Working Group

Recommendations for Improving Serum Creatinine Measurement: An Update

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NKDEP Lab Working Group
Key Recommendations for IVD Manufacturers & Clinical Laboratories

Interim recommendations until a revised GFR estimating equation is available

- **Implement the MDRD equation now for creatinine methods that are not re-calibrated to be traceable to IDMS**
- **For re-calibrated creatinine methods:**
  - **Add 0.1 mg/dL (8.8 µmol/L) to the creatinine value in the MDRD equation to be similar to the bias that existed in the MDRD study lab**

NKDEP Lab Working Group
Key Recommendations for IVD Manufacturers & Clinical Laboratories

Long-term recommendations

- **IVD manufacturers and clinical labs should coordinate introduction of re-calibration to coincide with a revised GFR estimating equation based on creatinine values traceable to IDMS**
  - **NKDEP will have a revised equation in 2005**
- **Clinical laboratories should report estimated GFR as >60 ml/min/1.73m2 when values are above 60**
- **Report serum creatinine values as mg/dL to two decimal places. Values reported as µmol/L should be reported as the nearest whole number.**

NKDEP Lab Working Group
Key Recommendations

- **IVD manufacturers should target optimal creatinine method performance at 1.0 mg/dL (88 µmol/L), and ensure comparable trueness and precision throughout the AMR**
- **Precision at lower creatinine concentrations needs to be improved to allow acceptable GFRest at values >60 mL/min/1.73m^2 , and for pediatric populations**
- **After re-calibration to IDMS, a realistic total error goal for creatinine is a maximum 10% increase in the relative error of the estimated GFR**
  - **Typical values: bias <5%, and CV <8%, at creatinine ≥1.0 mg/dL (88 µmol/L)**
- **IVD manufacturers must address analytical non-specificity in current routine methods**

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Key Recommendations for NKDEP in Collaboration with other Professional Organizations

- **Identify the impact on clinical decision criteria that may result from re-calibration of serum creatinine to be traceable to IDMS**
- **Develop a replacement for the MDRD eqn. that uses serum creatinine measurement traceable to IDMS**
- **Coordinate introduction of method traceability to IDMS with the appropriate GFR estimating equation**
- **Develop guidelines to implement appropriate GFR estimating equations for re-calibrated creatinine and to communicate the resultant changes in clinical interpretation of serum creatinine**

NKDEP Lab Working Group
Key Recommendations for NKDEP in Collaboration with other Professional Organizations

- **Communicate the clinical issues associated with re-calibrated serum creatinine**
  - **Reference interval change**
  - **Creatinine clearance values and reference interval change**
  - **Pharmacy impact on drug dose adjustment**
  - **Pediatric GFR estimating equations**
- **Coordinate with PT/EQAS providers to ensure appropriate grading adjustments are made during transition to IDMS traceability**
- **Establish a small group of reference labs that can perform high throughput reference measurement procedures**
- **Implement educational programs on the proper use of the MDRD equation to assess CKD risk.**

NKDEP Lab Working Group
Key Recommendations for National Metrology Institutes, reference laboratories, and members of JCTLM

- **Provide tools to assist IVD manufacturers to reduce analytical bias, since many routine methods can meet or exceed the imprecision goal of <8%**
  - **By the end of 2005, develop commutable reference materials for serum creatinine (NIST SRM 967 is expected to fulfill this need when available)**
  - **By the end of 2005, make available LC-IDMS reference method. Additional reference laboratories will be needed to meet the anticipated demand**

NKDEP Lab Working Group
Key Recommendations for PT and EQAS Providers

- **Introduce a regularly recurring proficiency program that uses commutable serum materials with target values traceable to IDMS reference measurement procedures**
  - **Permits an ongoing assessment of routine method performance and the evaluation of accuracy transfer processes used by manufacturers**
  - **The CAP Creatinine Accuracy Calibration Verification/Linearity Survey, LN24, has these attributes**